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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,757	06/25/2001	John E. Ahern	B0410/7282D1	2885
22832 7590 04/27/2007 Kirkpatrick & Lockhart Preston Gates Ellis LLP STATE STREET FINANCIAL CENTER One Lincoln Street BOSTON, MA 02111-2950			EXAMINER WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/27/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

09/888,757

Applicant(s)

AHERN ET AL.

Examiner

Catherine S. Williams

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-38 is/are pending in the application.
- 4a) Of the above claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION*****Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/16/07 has been entered.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-27 and 29-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wappler (USPN 2,269,963) in view of Campbell et al (USPN Re.34,936). Regarding claims 20 and 33, Wappler discloses an apparatus for carrying a plurality of sequentially positioned pellets (20) comprising a therapeutic agent (radioactive) and sequentially implanting one or more of the pellets within a tissue wall. See 1:6-7. The device includes an elongate body (32), a delivery chamber (22) having a space for the pellets (see figure 9) and a port (23), an actuator (39), and a distal end that is sharp and can penetrate a tissue wall. See element 23 and figure 2.

Regarding claims 21 and 34, see trigger 38.

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Regarding claims 22 and 35, see handle 37 which can be held and moved to turn the distal end to guide the device through a body lumen if one so chooses.

Regarding claim 23, the distal end of the device and the elongate body appear to be of a size and dimension that are capable of being inserted into a vessel of the body or into the interior of the heart if one so chooses.

Regarding claim 24, see tubular chamber 22 and 3:4.

Regarding claim 25, the distal end of the device is beveled and designed to penetrate tissue. See 3:10-12.

Regarding claims 26 and 36, see plunger 40.

Regarding claims 27 and 37, see ratchet assembly 41.

Regarding claim 29, see figure 9.

Regarding claims 30 and 38, see figure 2 and handle 37.

Regarding claim 31, see tubular (arcuate) chamber 22.

Regarding claim 32, see figure 9 element 24 and 3:12-22.

Wappler meets the claim limitations as described above but fails to include the elongate body being a flexible body. However, Campbell teaches a device for sequential delivery of pellets into a body having a sharp distal tip for delivering the pellets. As shown in figure 9, the device has an elongate flexible body (25) that is made from plastic resin (see 4:10-17).

At the time of the invention, it would have been obvious by one skilled in the art to make the elongate body (32) of Wappler from a plastic resin that is injection molded about tube 31 as taught by Campbell. In light of the fact that Wappler is silent as to the materials used to

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manufacture the device, one skilled in the art would recognize that plastic is a preferred material in the art due to its weight and ease of manufacture. The motivation for the incorporation would have been in order to use a known material to achieve the prior art device.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wappler in view of Dragan (USPN 4,457,712). Wappler meets the claim limitations with respect to claim 20 above but fails to include the threaded plunger of claim 28.

However, Dragan discloses an injection device that include both the teach of a plunger with ratchets and threads. See figures 6 and 17.

At the time of the invention, it would have been obvious by one skilled in the art to substitute the ratchets of Wappler for the threads as taught by Dragan. One skilled in the art would recognize that both threads and ratchets are designed to move the plunger from one end to another in order to dispense a material. However, one skilled in the art would recognize that threads provide the ability to move the plunger in smaller increments; thereby, enhancing the control of the movement of the plunger. The motivation for the substitution would have been in order to enhance the control of the movement of the plunger for dispensing the material.

### ***Response to Arguments***

Applicant argues that the prior art does not teach the elongate flexible body having a length and flexibility sufficient to allow for transluminal delivery of a pellet to the tissue wall. However, the prior art device is capable of puncturing the skin and passing through a lumen of the body to a tissue site. The prior art device is capable in size and shape of passing through at least a small portion of a lumen of a body vessel, e.g. the aorta via a variety of introduction

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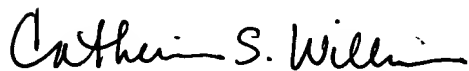
techniques including a puncture technique, to deliver the pellet within a tissue wall, e.g. the heart.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571/2724970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571/2724977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams  
April 25, 2007

CATHERINE S. WILLIAMS  
PRIMARY EXAMINER